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MAR 28 2006

SYBRON DENTAL SPECIALTIES

Section III - 510(k) Summary of Safety and Effectiveness

Submitter:

Sybron Dental Specialties, Inc.
100 Bayview Circle, Suite 6000
Newport Beach, California 92660
(949) 255-8766 - Phone
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Colleen Boswell - Contact Person

Date Summary Prepared: February 2006

Device Name:

- Trade Name - *Optibond All-In-One*
- Common Name - Resin Tooth Bonding Agent
- Classification Name - Resin Tooth Bonding Agent, per 21 CFR § 872.3200

Devices for Which Substantial Equivalence is Claimed:

- GC America, Inc., *G-Bond*

Device Description:

OptiBond All-In-One self-etching adhesive combines the ingredients needed for etching, priming, and bonding into a single adhesive solution, thereby eliminating separate etching and priming steps of the bonding process. *OptiBond All-In-One* adhesive can be used for the bonding of both direct and indirect restorations. The advantages of using *OptiBond All-In-One* adhesive include simplified bonding procedures and reduced post-operative sensitivity. *OptiBond All-In-One* incorporates the proven GPDM adhesive technology used in *Optibond Solo Plus*, fillers that contain fluoride and nano-fillers. This unique technology ensures the highest level of protection against microleakage while providing high bond strengths to a variety of substrates.

Intended Use of the Device:

The intended use of *Optibond All-In-One* is used for direct situations, i.e., light-cured composite and compomer restorations, composite/ceramic/amalgam/metal repairs, cavity sealing for amalgam restorations, light-cured or dual-cured core build-ups, and indirect situations, i.e., veneers, porcelain, composite, and metal-based inlays, onlays, crowns, bridges, endodontic posts, and cavity sealing as a pretreatment for indirect restorations.

Substantial Equivalence:

Optibond All-In-One is substantially equivalent to other legally marketed devices in the United States. The self-etching adhesive marketed by GC America, Inc. functions in a manner similar to and is intended for the same use as the product manufactured by Kerr Corporation.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAR 28 2006

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Colleen Boswell
Director, Corporate Compliance
Sybron Dental Specialties, Incorporated
100 Bayview Circle, Suite 6000
Newport Beach, California 92660

Re: K060469
Trade/Device Name: Optibond All-In-One
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: II
Product Code: KLE
Dated: February 22, 2006
Received: February 23, 2006

Dear Ms. Boswell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Chiu S. Lin', with a stylized flourish at the end.

Chiu S. Lin, PhD

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Section I

Indications for Use

510(k) Number (if known): K060469

Device Name: *OptiBond All-In-One*

Indications For Use:

OptiBond All-In-One is a self-etching adhesive which combines the ingredients needed for etching, priming, and bonding into a single adhesive solution and is used for direct situations, i.e., light-cured composite and compomer restorations, composite/ceramic/amalgam/metal repairs, cavity sealing for amalgam restorations, light-cured or dual-cured core build-ups, and indirection situations, i.e., veneers, porcelain, composite, and metal-based inlays, onlays, crowns, bridges, endodontic posts, and cavity sealing as a pretreatment for indirect restorations.

Prescription Use ☒
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)



Concurrence of CDRH, Office of Device Evaluation (ODE)

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Susan R. Meyer
Director, General Hospital,
Control, Dental Devices

K060469